510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number: k042443

B. Purpose for Submission: Notification of intent to manufacture and market the device: SpotChem EZ Total Cholesterol, HDL Cholesterol, Triglyceride and Lipid Panel Strip (Total Cholesterol, HDL and Triglyceride on one strip)

C. Measurand: Total Cholesterol, Triglyceride, HDL Cholesterol

D. Type of Test: Quantitative Colorimetric

E. Applicant: Polymedco, Inc

F. Proprietary and Established Names: Common Names – Total Cholesterol, Triglyceride, HDL-Cholesterol Proprietary Names – SPOTCHEM Total Cholesterol, SPOTCHEM Triglyceride, SPOTCHEM HDL Cholesterol, SPOTCHEM Lipid Panel Strip

G. Regulatory Information:

1. Regulation section: Total Cholesterol – 21 CFR 862.1175, Triglyceride – 21 CFR 862.1705, HDL Cholesterol – 21 CFR 862.1475

2. Classification: Class I, meets limitations of exemptions 21 CFR 862.9 (c)(4)

3. Product code: Total Cholesterol – CHH, Triglyceride – CDT, HDL Cholesterol – LBS

4. Panel: 75 (Chemistry)

H. Intended Use:

1. Intended use(s): The SpotChem EZ Total Cholesterol, HDL Triglyceride, and SPOTCHEM Lipid Panel Strip test and panel system are an in vitro diagnostic procedure intended to measure Total Cholesterol/HDL/Triglyceride quantitatively in human serum and plasma on the SpotChem EZ Analyzer

2. Indication(s) for use: Total Cholesterol measurements are used in the diagnosis and treatment of lipid and lipoprotein metabolism disorders.

Triglyceride measurements are used in the diagnosis and treatment of

patients with diabetes mellitus, nephrosis, liver obstruction and other diseases involving lipid metabolism or various endocrine disorders.

HDL Cholesterol measurements are used in the diagnosis and treatment of lipid and lipoprotein metabolism disorders.

3. Special conditions for use statement(s): For prescription use only

4. Special instrument requirements: These assays are intended for use on the SpotChem EZ analyzer.

I. Device Description: The Polymedco, Inc SPOTCHEM Cholesterol, Triglyceride, HDL Cholesterol and Lipid Panel Strip are in vitro diagnostic procedures intended to measure Total Cholesterol/HDL/Triglyceride quantitatively in human serum and plasma on the SpotChem EZ Analyzer.

The device is composed of plastic strips to which a multilayered test field is affixed. The layers consist of a sample retention layer, a layer containing the reagents and a support layer. Twenty five strips and one calibration card are packaged together.

The Lipid Panel Strip consists of a Cholesterol, Triglyceride and HDL Cholesterol Assay on one strip.

J. Substantial Equivalence Information:

1. Predicate device name(s): HDL kit, Bayer Advia 1650, Total Cholesterol kit, Bayer Advia 1650, Triglyceride kit, Bayer Advia 1650

2. Predicate 510(k) number(s): k982341, k923504, k923508

3. Comparison with predicate:

	Total cholesterol	HDL Cholesterol	Triglycerides
Predicate Methodology	colorimetric enzyme-based	colorimetric enzyme-based	Colorimetric enzyme-based
Test Methodology	colorimetric enzyme-based	colorimetric enzyme-based	Colorimetric enzyme-based
Predicate Reagent Storage	2-8°C	2-8°C	2-8°C
Test Reagent Storage	2-8°C	2-8°C	2-8°C
Predicate Sample types	Serum/Plasma, Whole blood	Serum/Plasma, Whole blood	Serum/Plasma, Whole blood
Test Sample Types	Serum/Plasma, Whole blood	Serum/Plasma, Whole blood	Serum/Plasma, Whole blood

Predicate Controls	Recommended	Recommended	Recommended
Test Controls	Recommended	Recommended	Recommended
Correlation with Predicate device	N = 93. Samples spanned from 73 mg/dL to 309 mg/dL. The regression equation was y = 0.927x + 6.04 and r = 0.992	N = 55. Samples spanned from 21 mg/dL to 87 mg/dL. The regression equation was y = 0.9097 + 3.86 and r = 0.966	N = 80. Samples spanned from 64.8 mg/dL to 203.4 mg/dL. The regression equation was y = 1.0253x – 0.0893 and r = 0.993.

K. Standard/Guidance Document Referenced (if applicable): Cholesterol and HDL Cholesterol were certified by the Cholesterol Reference Method Laboratory Network (CRMLN) as meeting the National Cholesterol Program's (NCEP) performance criteria for accuracy and precision.

L. Test Principle: The Total Cholesterol, HDL Cholesterol and Triglyceride assays are based on established colorimetric procedures.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Intra-assay precision was assessed by assaying three samples twenty times in one run. The results are presented in the table below:

Intra Assay Precision on Spot Chem Analyzer. Results reported in mg/dL.

Analyzer Poly Chem		**Level 1**	**Level 2**	**Level 3**
Total Cholesterol	n	20	20	20
	Mean	132	166	246
	SD	2.49	3.08	7.74
	%CV	1.88	1.86	3.15
HDL	Mean	40.5	55.9	92.3
	SD	1.27	1.57	3.42
	%CV	3.15	2.81	3.71
Triglyceride	Mean	98.7	167.7	394.5
	SD	3.15	3.53	11.48
	%CV	3.19	2.10	2.91

Interassay precision was assessed by assaying three samples in duplicate in ten runs over ten days. The results are presented below.

Inter Assay Precision on Poly-Chem Analyzer. Results reported in mg/dL.

Analyzer Poly Chem		**Level 1**	**Level 2**	**Level 3**
Total Cholesterol	Days	10	10	10
	n	20	20	20
	Mean	132	168	245
	SD	2.67	2.69	11.64
	%CV	2.02	1.60	4.75
HDL	Mean	26.2	46.1	69.8
	SD	2.10	3.38	5.80
	%CV	8.00	7.34	8.31
Triglyceride	Mean	93.8	166.8	389.4
	SD	4.31	5.33	14.14
	%CV	4.59	3.19	3.63

b. *Linearity/assay reportable range:* The linearity was assessed by assaying serial dilutions. The linearity claim is based on a percent deviation of ≤5% at the two highest concentrations. The results obtained were as follows: Total Cholesterol 50 – 400 mg/dL, HDL Cholesterol 10 – 122 mg/dL and Triglyceride 9.6 – 507 mg/dL.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):* Polymedco has documented traceability to the National Cholesterol Education Program's recommended accuracy base for Total Cholesterol and HDL Cholesterol by performing a direct comparison with a Cholesterol Reference Method Laboratory Network laboratory using fresh human specimens which cover the NCEP medical decision points.

d. *Detection limit:* Functional sensitivity was assessed by diluting a pool of 10 different concentrations below the lower limit of the analyte range. Three runs were performed over three different days on the SpotChem EZ analyzer. The mean, standard deviation and coefficient of variation was calculated for the ten replicates of each dilution. The functional sensitivity of the test was defined as the value of the dilution where the CV is approximately 20% (taking into consideration that the actual mean was within ± 10% of the expected target). It was determined as follows: 33mg/dL with a CV reported at 4.5% for Total Cholesterol, 8.2 mg/dL with a CV of 4.1% for HDL, and 9.6mg/dL with a CV reported at 5.4% for Triglyceride.

e. *Analytical specificity:* Studies were performed to assess common or known substances that could interfere with the method. A summary of the data for known interferents appears for the common interferents in the table below:

	Total Cholesterol	HDL	Triglyceride
Sample	**Highest Level Tested with No Interference**	**Highest Level Tested with No Interference**	**Highest Level Tested with No Interference**
Hemoglobin	500 mg/dL	50 mg/dL	350 mg/dL
Bilirubin	9 mg/dL	3.0 mg/dL	3.0 mg/dL
Triglycerides	200 mg/dL	200 mg/dL	

f. *Assay cut-off:* N/A

2. Comparison studies:

a. *Method comparison with predicate device:* A clinical correlation study was performed comparing the Total Cholesterol, HDL and Triglyceride tests and Total Cholesterol, HDL and Triglyceride strip results generated by the SpotChem against the results from the Bayer Advia. Additionally, the Total Cholesterol and HDL cholesterol reagent systems were certified by CRMLN. The comparison with the predicate device yielded the following results: Total Cholesterol - $N = 93$, samples spanned from 73 mg/dL to 309 mg/dL, regression equation was Y = 0.927x + 6.04 and r = 0.992; HDL Cholesterol - N = 55, samples spanned from 21 mg/dL to 87 mg/dL, regression equation was Y = 0.9097 + 3.86 and r = 0.966; Triglycerides - N = 80, samples spanned from 64.8 mg/dL to 203.4 mg/dL, regression equation was Y = 1.0253x – 0.0893 and r = 0.993.

b. *Matrix comparison:* A clinical correlation study was performed comparing the Total Cholesterol, HDL and Triglyceride test results generated against the results generated from whole blood samples when performed on the SPOTCHEM EZ Analyzer. The HDL regression equation was Y = 1.123x +0.9756 and r^2= 0.981344, N=29. For Total Cholesterol Serum and Whole Blood Comparison the regression equation was Y = 1.0108x - 4.3387 and r^2= 0.9668, N=29. For Triglycerides Serum and Whole Blood Comparison the regression equation was Y = 2.623x + 1.050x and r^2= 0.9993, N=31.

3. Clinical studies:

a. *Clinical Sensitivity:* N/A

b. Clinical specificity: N/A

c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off**:** N/A

5. Expected values/Reference range:

Cholesterol - (NCEP guidelines)
Risk levels

Value	Interpretation
< 200 mg/dL (5.17 mMol/L)	Desirable blood cholesterol
200-239 mg/dL (5.17 - 6.18 mMol/L)	Borderline-high blood cholesterol
≥ 240 mg/dL (6.20 mMol/L	High blood cholesterol

Normal Triglyceride Values[1]: 50 - 130 mg/dL (0.56 - 1.47 mmol/L)

The following upper limits are recommended for the determination of the risk factor hypertriglyceridemia:
Borderline-high from: 150 mg/dL or (1.71 mmol/L)
High from: 200 mg/dL or (2.29 mmol/L)
Very high: ≥500 mg/dL or (5.64 mmol/L)

HDL Cholesterol - (NCEP guidelines)

mg/dL	mMol/L	
≤ 40	≤1.04	Low
≥60	≥1.55	High

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

[1] J of Am. Med. Assoc. 1984,251:1196-2000